

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

*This Document Relates To All Actions*  
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ORDER NO. 13

13-MD-2434 (CS)(LMS)  
13-MC-2434 (CS)

**FIRST AMENDED AGREED ORDER REGARDING PROPER PARTY-DEFENDANT  
AND  
ABBREVIATED SERVICE PROCEDURES FOR SERVICE UPON DEFENDANTS  
BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER OY, AND  
BAYER PHARMA AG**

Seibel, J.

**I. Scope of Order**

This Order applies to claims brought by a U.S. citizen or resident based on usage or purchase of Mirena<sup>®</sup> (“Mirena”) in the United States in which the claimed injury allegedly resulted from the perforation, embedment, or migration of the Mirena and (i) currently are pending in MDL No. 2434 or (ii) will be filed in, removed to or transferred to this Court.

**II. Proper Party-Defendant Stipulation for U.S. Defendant**

A. Some plaintiffs have named the following U.S. defendants in lawsuits involving Mirena: Bayer Corporation; Bayer HealthCare, LLC; Bayer Pharmaceuticals Corporation; Bayer HealthCare Pharmaceuticals Inc. (BHCP); Berlex Laboratories, Inc.; and Berlex, Inc. (“Bayer/Berlex entities”).

B. Bayer HealthCare Pharmaceuticals Inc. admits that on April 4, 2007, as part of a corporate acquisition, the name of Berlex, Inc. was changed to Bayer HealthCare Pharmaceuticals, Inc.

C. Bayer HealthCare Pharmaceuticals Inc. admits that, at certain times it designed, developed, marketed, distributed, advertised, promoted and/or sold Mirena<sup>®</sup> in the United States.

D. Bayer HealthCare Pharmaceuticals Inc., admits that at no time has it manufactured Mirena®.

E. Bayer HealthCare Pharmaceuticals Inc. is the proper domestic party in lawsuits involving Mirena inserted in the United States. Its principal place of business is in New Jersey.

F. Accordingly, to the extent that a plaintiff recovers a judgment in a lawsuit for injuries allegedly caused by Mirena, Bayer HealthCare Pharmaceuticals Inc. stipulates that it is the proper party to the lawsuit and it will not raise any defenses that any of the Bayer/Berlex entities named above or any other Bayer/Berlex entity(ies) with a principal place of business in the United States are/were the proper party to the lawsuit.

G. The Bayer/Berlex entities named above agree that, should documents, materials or witnesses concerning Mirena be in its possession, custody or control, these will be subject to production and/or examination as if they were in the possession, custody or control of Bayer HealthCare Pharmaceuticals Inc. and that such production will be obtained and made by Bayer HealthCare Pharmaceuticals Inc.

H. In the event that a plaintiff needs to later add one of the Bayer/Berlex entities named above other than Bayer HealthCare Pharmaceuticals Inc. into a Mirena lawsuit, the Bayer/Berlex entities named above will waive any statute of limitations defenses based upon the expiration of time after the filing of the original lawsuit. Of course, they will reserve any limitations defenses they may have had at the time of the original filing.

I. In exchange for this stipulation, plaintiffs agree to voluntarily dismiss all Bayer/Berlex entities named above other than Bayer HealthCare Pharmaceuticals Inc. in all cases filed prior to this Order and subject to this Court's jurisdiction. All stipulations of dismissal are without prejudice and without costs to any party.

J. In addition, plaintiffs subject to the jurisdiction of this Court will not sue any of the Bayer/Berlex entities named above other than Bayer HealthCare Pharmaceuticals Inc. in future cases regarding Mirena in MDL 2434 and will not seek default judgment against any Bayer/Berlex entity named above other than Bayer HealthCare Pharmaceuticals Inc. for failure to answer a Mirena related lawsuit.

### **III. Proper Party Stipulation for Foreign Defendants**

A. Some plaintiffs have named or may name the following foreign defendants in lawsuits involving Mirena: Bayer Oy, Bayer Pharma AG (BPAG), Schering AG, Bayer AG, Bayer HealthCare AG, Bayer Gesellschaft fuer Beteiligungen mbH, and Bayer Nordic SE (collectively the “foreign Bayer entities”).

B. Bayer Oy and Bayer Pharma AG are the proper foreign parties for lawsuits involving Mirena. These entities respectively have their principal place of business in Finland and Germany.

C. Bayer Oy admits that it designed, developed, researched, manufactured and tested all Mirena® sold by BHCP in the United States.

D. Bayer Oy further admits that it sold Mirena® directly to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena® to Bayer Pharma AG, which resold the product to BHCP.

E. Bayer Pharma AG admits that it designed, developed, and researched all Mirena® sold by BHCP in the United States. Bayer Pharma AG further admits that, from September 1, 2008, it purchased all Mirena® sold in the United States exclusively from Bayer Oy and resold the product to BHCP.

F. BHCP admits that, prior to September 1, 2008, it and its predecessors purchased all Mirena® sold in the United States from Bayer Oy and its predecessors. After September 1, 2008,

BHCP purchased all Mirena® sold in the United States from Bayer Pharma AG, which purchased the product from Bayer Oy.

G. Accordingly, to the extent that a plaintiff recovers a judgment in a lawsuit for injuries allegedly caused by Mirena, Bayer Oy and Bayer Pharma AG stipulate that they are the proper party to the lawsuit and will not raise any defenses that any other foreign Bayer entity(ies) with a principal place of business outside the United States are/were the proper party to the lawsuit.

H. Plaintiffs agree to voluntarily dismiss all foreign Bayer entities named above other than Bayer Oy or Bayer Pharma AG in all cases filed prior to this Order and subject to this Court's jurisdiction. All stipulations of dismissal are without prejudice and without costs to any party.

I. Plaintiffs subject to the jurisdiction of this Court will not sue any "foreign Bayer entities", as defined in III.A, other than Bayer Oy and Bayer Pharma AG in future cases regarding Mirena in MDL 2434 and will not seek default judgment against any "foreign Bayer entity" named above.

J. In the event that a plaintiff needs to later add one of the "foreign Bayer entities" named above other than Bayer Oy and Bayer Pharma AG into a Mirena lawsuit, the "foreign Bayer entities", as defined in III.A, will waive any statute of limitations defenses based upon the expiration of time after the filing of the original lawsuit. Of course, they will reserve any limitations defenses they may have had at the time of the original filing.

K. Further, Bayer Pharma AG and Bayer Oy are not required to file responsive pleadings separate from those of Bayer Healthcare Pharmaceuticals, Inc. because all parties may respond (if required) via a single pleading. Such pleadings shall be treated as though filed individually by each party.

#### **IV. Service of Process**

A. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Oy, and Bayer Pharma AG (“proper parties”) agree to waive formal service of summons on it pursuant to Federal Rule of Civil Procedure 4 and to accept service of process on it pursuant to the terms of this Order in Mirena cases that are properly commenced in, removed to, or transferred to this MDL. Bayer HealthCare Pharmaceuticals Inc., Bayer Oy, and Bayer Pharma AG invoke all benefits provided by Federal Rule of Civil Procedure 4 to defendants who waive service of a summons. Bayer HealthCare Pharmaceuticals Inc., Bayer Oy, and Bayer Pharma AG do not intend to waive any defenses available to them by waiving service of process.

B. These procedures for informal service of process are not available in cases in which the plaintiff seeks remand to state court unless and until remand is denied. All deadlines set forth in Part IV of this Order run from the date on which remand is denied.

C. Further, these procedures are only available in those cases where the claimed injury allegedly resulted from the perforation, embedment, or migration of Mirena.

D. Further, these procedures for informal service of process upon Bayer Oy and Bayer Pharma AG are only available in cases where plaintiff also files suit against Bayer Healthcare Pharmaceuticals, Inc.

E. Service upon Bayer Pharma AG and Bayer Oy shall be mailed via **REGISTERED** mail, as set forth in IV.F.2 and IV.F.3, no less than (7) calendar days **after** mailing of service upon Bayer Healthcare Pharmaceuticals, Inc. via **CERTIFIED** mail, as set forth in IV.F.1.

F. Plaintiffs whose Complaints are not subject to IV.B and meet the requirements of IV.C who choose not to serve the proper parties through original process shall have sixty (60) days after the date a case is docketed in any United States District Court to serve the Complaint together with a Summons as follows:

1. By **CERTIFIED** Mail, Return Receipt Requested, upon the following representative of Bayer HealthCare Pharmaceuticals Inc.:

SOP Department  
Corporation Service Company  
Suite 400  
2711 Centerville Road  
Wilmington, DE 19808

2. By **REGISTERED** Mail, Return Receipt Requested, upon the following representative of Bayer Pharma AG:

Bayer Pharma AG  
Attn: Eva Gardyan-Eisenlohr  
General Counsel  
Muellerstrasse 178  
13353 Berlin  
GERMANY

3. By **REGISTERED** Mail, Return Receipt Requested, upon the following representative of Bayer Oy:

Bayer Oy  
Legal Department  
Pansiontie 47 / P.O. Box 415  
20101 TURKU  
FINLAND

G. Plaintiffs who have already filed Complaints that are not subject to IV.B, meet the requirements of IV.C, and chose not to serve the proper parties through original process shall have sixty (60) days from the date of this Order to serve the Complaint together with a Summons as follows:

1. By **CERTIFIED** Mail, Return Receipt Requested, upon the following representative of Bayer HealthCare Pharmaceuticals Inc.:

SOP Department  
Corporation Service Company  
Suite 400  
2711 Centerville Road  
Wilmington, DE 19808

2. By **REGISTERED** Mail, Return Receipt Requested, upon the following representative of Bayer Pharma AG:

Bayer Pharma AG  
Attn: Eva Gardyan-Eisenlohr  
General Counsel  
Muellerstrasse 178  
13353 Berlin  
GERMANY

3. By **REGISTERED** Mail, Return Receipt Requested, upon the following representative of Bayer Oy:

Bayer Oy  
Legal Department  
Pansiontie 47 / P.O. Box 415  
20101 TURKU  
FINLAND

H. Service will be effective only if addressed as above. General mailing to Bayer HealthCare Pharmaceuticals Inc., Bayer Oy or Bayer Pharma AG, or use of other methods of transmission, including but not limited to Federal Express or e-mail, will not be sufficient to effect service.

I. Service on BHCP, pursuant to the process set forth above shall be effective as of the date BHCP's representative identified in IV.E and IV.F receives the certified mail.

J. Service on Bayer Oy or Bayer Pharma AG pursuant to the process set forth above shall be effective ten (10) days after mailing provided the requirements of paragraph IV.G through IV.K have been met.

K. Contemporaneous with mailing the Bayer Oy or Bayer Pharma AG pleading, plaintiffs shall provide, by electronic mail, notice of service including a copy of the complaint to the following address: [mirenacomplaints@shb.com](mailto:mirenacomplaints@shb.com)

L. Should Bayer be required to file a responsive pleading, plaintiffs agree to extend Bayer HealthCare Pharmaceuticals Inc.'s, Bayer Oy's, and Bayer Pharma AG's responsive pleading

deadline by sixty (60) days after the date of service or as otherwise agreed upon or directed by the Court. Other than those based on formal service of process, Bayer HealthCare Pharmaceuticals Inc., Bayer Oy, and Bayer Pharma AG reserve all other rights and defenses available to it under federal or state law and under applicable treaties and conventions.

M. Prior to moving to dismiss a case for a defect in service under Parts IV.D and IV.E, Bayer HealthCare Pharmaceuticals Inc., Bayer Oy, and Bayer Pharma AG shall serve notice via a single paged letter without attachment, identifying the specific defect(s), on plaintiff's counsel and provide 30 (thirty) days for plaintiff to cure the defect(s).

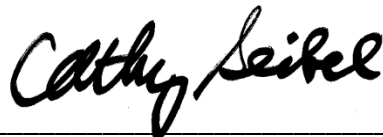
N. For complaints filed prior to the entry date of this amended Order, where plaintiffs have named and served Bayer Healthcare Pharmaceuticals, Inc. and have named, but not served, Bayer Oy or Bayer Pharma AG, defendants agree to extend any applicable time limitations in Fed. R. Civ. P. 4(m) until March 31, 2014. Nothing in this Order shall be construed to in any way limit, extend, or otherwise modify the applicable statute of limitations.

O. Any counsel who effects service of a case through this agreement agrees not to seek discovery in that case of any of the named foreign entities in III.A in any court other than the United States District Court for the Southern District of New York, MDL 2434 or Superior Court of New Jersey, Law Division, Bergen County, MultiCounty Litigation Case No. 297.

**SO ORDERED.**

Dated: February 26, 2014

White Plains, New York

A handwritten signature in black ink that reads "Cathy Seibel". The signature is written in a cursive, flowing style. Below the signature is a solid horizontal line.

CATHY SEIBEL, U.S.D.J.